ATTACHMENT 52

U.S. FOOD & DRUG ADMINISTRATION

November 16, 2021

Chris Gibson
Chief Operations Officer
Rebotix Repair, LLC
539 Pasadena Avenue South
St. Petersburg, FL 33707

Document Number: CPT2000126

Dear Mr. Gibson:

It has come to our attention that you may be remanufacturing the da Vinci S EndoWrist Instruments, which appears to meet the definition of a device as that term is defined in section 201(h) of the Federal Food Drug and Cosmetic Act (FD&C Act), in a manner that potentially violates the FD&C Act.

Specifically, we have conducted a review of our files, and have been unable to identify any Food and Drug Administration (FDA) clearance or approval number for the da Vinci S EndoWrist Instruments to support the services described on your website (https://rebotixrepair.com/) and described in a prior email communication to the Agency dated March 19, 2020.

Specifically, the da Vinci S EndoWrist Instruments were cleared for a set number of uses. By extending the number of uses, your activities may be altering the intended use of the subject device. We have conducted a review of our files and are unable to identify an additional Food and Drug Administration (FDA) clearance or approval supporting this intended use.

We request that you provide us with the following information:

- FDA clearance or approval number for the remanufactured da Vinci S EndoWrist Instruments.
- Prior submission numbers, if previously withdrawn or found not substantially equivalent, related to your activities with the da Vinci S EndoWrist Instruments.
- The basis for your determination of whether or not you are required to obtain FDA clearance or approval for the da Vinci S EndoWrist Instruments.

In addition, we request that a written response be submitted within 30 days of receipt of this letter. The response and any further correspondence regarding this matter should reference the Document Number, listed above, and should be submitted to:

Food and Drug Administration
Allegations of Regulatory Misconduct Team, WO66-1523

Exhibit
DX 268

10903 New Hampshire Avenue
Silver Spring, MD 20993

Or, electronically to: CDRHDeviceAllegations@fda.hhs.gov

If you have questions relating to this matter, you may contact Anthony Lee, PhD at 240-402-5935, or log onto our web site at www.fda.gov for general information relating to FDA device requirements.

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2021.11.16 14:22:26 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT 4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health